



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

APR 18 2012

Re: EGRIFTA
Docket No.: FDA-2011-E-0153

The Honorable David J. Kappos
Undersecretary of Commerce for Intellectual Property
Director of the United States Patent and Trademark Office
Mail Stop Hatch-Waxman PTE
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Director Kappos:

This is in regard to the application for patent term extension for U.S. Patent No. 5,861,379, filed by Theratechnologies, Inc., under 35 U.S.C. section 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for EGRIFTA (tesamorelin acetate), the human drug product claimed by the patent.

The total length of the regulatory review period for EGRIFTA (tesamorelin acetate) is 3,284 days. Of this time, 2,753 days occurred during the testing phase and 531 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: November 15, 2001.

FDA has verified the applicant's claim that the date the investigational new drug application became effective was on November 15, 2001.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: May 29, 2009.

FDA has verified the applicant's claim that the new drug application (NDA) for EGRIFTA (NDA 22-505) was submitted on May 29, 2009

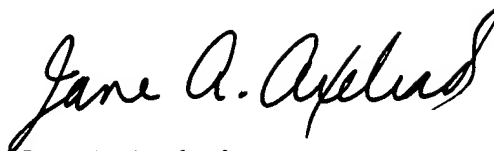
3. The date the application was approved: November 10, 2010.

FDA has verified the applicant's claim that NDA 22-505 was approved on November 10, 2010.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. section 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

A handwritten signature in black ink, reading "Jane A. Axelrad". The signature is fluid and cursive, with the first name "Jane" and last name "Axelrad" clearly legible.

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

cc: Doanna Goldenson
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